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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,614	01/31/2007	Manuela Teresa Raimondi	BJS-2149-199	8654
23117 7590 10/13/2011 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER CHOU, WILLIAM B	
			ART UNIT 3779	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/589,614	Applicant(s) RAIMONDI, MANUELA TERESA	
	Examiner WILLIAM CHOU	Art Unit 3779	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1,2,4-13 and 23-28 is/are pending in the application.
- 5a) Of the above claim(s) 14-22 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1,2,4-13 and 23-28 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Response to Arguments

1. Examiner acknowledges the receipt of the Applicant's Amendment dated June 20, 2011 (hereinafter "Amendment"). Applicant amended claims 1, 2, 4-13. Claims 14-22 are withdrawn. Applicant canceled claim 3. Applicant added new claims 23-28. Claims 1, 2, 4-13 and 23-28 are pending.
2. Applicant's arguments with respect to Claims 1, 2 and 4-13 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

3. Applicant has amended Claims 1, 9 and 12 and the objections are withdrawn.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Applicant has canceled **Claim 3** and the rejection under 35 USC 112 Second Paragraph is withdrawn.
6. Applicant has amended **Claims 9, and 11-13** and the rejections under 35 USC 112 Second Paragraph are withdrawn.

Claim Rejections - 35 USC § 103

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7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. **Claims 1, 2, 4-11, 13, 23 and 27** are rejected under 35 U.S.C. 103(a) as being unpatentable over Doi (U.S. Patent 6,033,359) and in further view of Ouichi (U.S. Patent 6,814,728).

9. **As to Claim 1**, Doi discloses **in Fig. 1** a similar surgical instrument for geometrical evaluation of an object inside a body of a human being or animal, the instrument comprising a handle **(13)**, a reference device **(3)** and means **(112(6) is invoked; a knob means (14) in Col. 3 Lines 24-30 of Doi that is pushed/pulled being analogous to trigger means for pushing/pulling as disclosed in the specification)** for bringing said reference device into the vicinity of said object, wherein said instrument is adapted to co-operate with an image acquisition device for acquiring at least one image of said reference device when it is in the vicinity of said object, wherein said ~~screen~~ reference device can be brought from a first fold up state to an unfolded state **(Col. 3 Lines 43-52)** and to a second fold up state **(Col. 3 Lines 58-63)**, wherein said unfolded state is the state when said screen is in the vicinity of said object and said at least one image is being acquired and wherein said second fold up state is the state when said screen is recalled.

10. Doi discloses the reference device capable of folding and unfolding, however remains silent as to the device comprising a screen. Ouichi is applied as a secondary

teaching to evidence the level of skill in the art. In particular, Ouichi teaches a similar reference device **(5) in Col. 9 Lines 33-37** that is foldable **(Col. 9 Lines 56-59)** and comprises a screen. In view of the teachings of Doi and Ouichi, as a whole, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the reference device of Doi with the reference device of Ouichi as an alternative implementation of analogous structures for the same purpose of measuring size.

11. **As to Claim 2**, Doi and Ouichi disclose the similar surgical instrument of Claim 1 discussed above, wherein Doi also discloses the adaptation of the invention to measure a lesion of an internal tissue as a "diseased part or the like" **in Column 1 Lines 6-8**.

12. **As to Claims 4 and 5**, Doi and Ouichi disclose the similar surgical instrument of Claim 1 discussed above. Doi remains silent as to the color of the reference device. Ouichi teaches that said screen has a color substantially contrasting with the object to be evaluated geometrically **in Col. 9 Lines 43-47** including dark grey or black **(non-red)**. In view of the teachings of Doi and Ouichi, as a whole, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the reference device of Doi with the reference device of Ouichi as an alternative implementation of analogous structures for the same purpose of measuring size.

13. **As to Claim 6**, Doi and Ouichi disclose the similar surgical instrument of Claim 1 discussed above, wherein Doi also discloses that said surgical instrument comprises a guide barrel **(shaded barrel in Fig. 2 and Col. 2 Lines 18-20)** and a shank **(1, 1', 2)** sliding inside said guide barrel, the barrel being able to be inserted inside the body and

having a proximal end in the vicinity of the handle and an opposite distal end which is open.

14. **As to Claims 7-9**, Doi and Ouichi disclose the similar surgical instrument of Claim 6 discussed above. Doi also discloses that the shank has a head-piece **(10, 12, 12a) of Fig.1 and Col. 2 Lines 62-27** with support arms **(4)** for supporting said screen. Additionally, Ouichi discloses that said screen is capable of being supported with support arms **(1, 2) in Fig. 2**. In view of the teachings of Doi and Ouichi, as a whole, it would have been obvious to one of ordinary skill in the art at the time of invention was made to not only modify the reference device of Doi with the screen of Ouichi as an alternative implementation of analogous structures for the same purpose, but also in such a way that the deformable screen is supported with the support arms of Doi.

15. **As to Claim 8**, Doi and Ouichi disclose the similar surgical instrument of Claim 7 discussed above, wherein Doi discloses that said support arms are pivotably mounted and are elastically movable **(pivoting motion between joints of the arms allow for elastic expansion and contraction motions)** between a first position where the screen is retracted and a second position where the screen is unfolded in the vicinity of the object to be evaluated.

16. **As to Claim 9**, Doi and Ouichi disclose the similar surgical instrument of Claim 6 discussed above. Doi discloses that said surgical instrument comprises a knob (14) wherein the shank is adapted to be moved from a position where the screen is retracted inside the barrel into a position where screen is unfolded in the vicinity of the object to be evaluated by means of said trigger situated at the proximal end, however remains

silent as to a trigger-like structure. Ouichi teaches a trigger (214) in Fig. 9 and Col. 11 Lines 1-6. In view of the teachings of Doi and Ouichi, as a whole, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the knob of Doi with the trigger of Ouichi as an alternative implementation of analogous structures for the same purpose of pushing/pulling motion.

17. **As to Claim 10**, Doi and Ouichi disclose the similar surgical instrument of Claim 1 discussed above, wherein Doi also discloses that it also comprises a recall system for recalling the reference device from said unfolded state into said second retracted state **in Column 3 Lines 36-63**.

18. **As to Claim 11**, Doi and Ouichi disclose the similar surgical instrument of Claim 10 discussed above, wherein Doi also discloses that the recall system comprises a wire **(11) of Col. 2 Lines 59-62** connected to the reference device and to the handle, said wire being slidable inside an axial cavity of a shank **(1, 1', 2)**.

19. **As to Claim 13**, Doi and Ouichi disclose the similar surgical instrument of Claim 1 discussed above. Doi also discloses that said instrument is at least partially made with polymer material **in Col. 2 Lines 28-30**.

20. **As to Claim 23**, Doi and Ouichi disclose the similar surgical instrument of Claim 1 discussed above. Ouichi also discloses that said screen, when in said unfolded state, has a circular shape **as shown in Fig. 1**.

21. **As to Claim 27**, Doi and Ouichi disclose the similar surgical instrument according to Claim 7 discussed above. Doi discloses **in Fig. 1 and Col. 2 Line 3** that the reference device is larger than 1.5mm and has square shaped meshes **(markings)**.

Ouichi discloses **in Col. 9 Line 34** that the screen can be 10mm in diameter and that and **in Fig. 7** that there are 12 divisions in the up/down direction and 14 divisions left/right, and thus having a size from 0.5 mm to 1.5 mm. In view of the teachings of Doi and Ouichi, as a whole, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the square shaped meshes of Doi with the sizing of Ouichi as an alternative implementation of analogous structures for the same purpose of measuring size.

22. **Claim 12** is rejected under 35 U.S.C. 103(a) as being unpatentable over Doi and Ouichi and in further view of Hinnenkamp (U.S. Patent 6,110,200).

23. **As to Claim 12**, Doi and Ouichi disclose the similar surgical instrument of Claim 1 discussed above. However, Doi and Ouichi remain silent as to said surgical instrument comprises a scissors type handle. Hinnenkamp is applied as a secondary teaching to evidence the level of skill in the art. In particular, Hinnenkamp teaches a similar surgical instrument that utilizes a trigger in a proximal end for contracting measurement means in a distal end **in Fig. 17**. In view of the teachings of Doi, Ouichi and Hinnenkamp, as a whole, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the means for bringing said reference device into the vicinity of said object of Doi with the scissors type handle of Hinnenkamp as an alternative implementation of analogous means for creating pushing/pulling motion.

24. **Claim 24** is rejected under 35 U.S.C. 103(a) as being unpatentable over Doi and Ouichi and in further view of Abe (U.S. Publication 2004/0220555).

25. **As to Claim 24**, Doi and Ouichi disclose the similar surgical instrument according to Claim 6 discussed above. Ouichi discloses that multiple screen sizes can be used **in Col. 10 Lines 13-15**. However, Doi remains silent as to the reference device being larger than a diameter of said guide barrel. Abe is applied as a secondary teaching to evidence the level of skill in the art. In particular, Abe teaches a similar reference device to Doi, wherein the reference device, when in said unfolded state, is larger than a diameter of said guide barrel **as shown in Fig. 4**. In view of the teachings of Doi, Ouichi and Abe, as a whole, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the reference device size of Doi and Ouichi with the reference device size of Abe as an alternative implementation of analogous structures for the same purpose of measuring size in order to measure larger lesions.

26. **Claims 25 and 26** are rejected under 35 U.S.C. 103(a) as being unpatentable over Doi and Ouichi and in further view of Tovey (U.S. Patent 5,405,360).

27. **As to Claims 25 and 26**, Doi and Ouichi disclose the similar surgical instrument according to Claim 7 discussed above. The prior art remains silent as to said screen connected to said support arms at distal sections, although this is well known in the art as evidenced by Tovey. Tovey is applied as a secondary teaching to evidence the level of skill in the art. In particular, Tovey teaches a similar surgical instrument, wherein said

screen is connected to said support arms at distal sections **as shown in Figs. 1-4**. In view of the teachings of Doi, Ouichi and Tovey, as a whole, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the reference device size of Doi and Ouichi to be connected at distal sections as taught by Tovey, as an exemplary implementation of analogous supporting arms and screen for deployment at the distal end being able to be retracted and deployed.

28. **As to Claim 26**, Doi and Ouichi disclose the similar surgical instrument according to Claim 11 discussed above. Doi discloses said wire connected to the center of the supporting arms and reference device, however does not explicitly disclose connection to said screen, although this is well known in the art as evidenced by Tovey. In particular, Tovey teaches a similar surgical instrument, wherein said wire **(12)** is connected to the center of said screen **in Fig. 2**.

29. **Claim 28** is rejected under 35 U.S.C. 103(a) as being unpatentable over Doi and Ouichi and in further views of Abe and Tovey.

30. **As to Claim 28**, Doi discloses **in Fig. 1** a similar surgical instrument for geometrical evaluation of an object inside a body of a human being or animal, the instrument comprising a handle **(13)**, a reference device **(3)** and means **(112(6) is invoked; a knob means (14) in Col. 3 Lines 24-30 of Doi that is pushed/pulled being analogous to trigger means for pushing/pulling as disclosed in the specification)** for bringing said reference device into the vicinity of said object, wherein said instrument is adapted to co-operate with an image acquisition device for acquiring

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at least one image of said reference device when it is in the vicinity of said object, wherein said ~~screen~~ reference device can be brought from a first fold up state to an unfolded state (**Col. 3 Lines 43-52**) and to a second fold up state (**Col. 3 Lines 58-63**), wherein said unfolded state is the state when said screen is in the vicinity of said object and said at least one image is being acquired and wherein said second fold up state is the state when said screen is recalled.

31. Doi discloses the reference device capable of folding and unfolding, however remains silent as to the device comprising a screen. Ouichi is applied as a secondary teaching to evidence the level of skill in the art. In particular, Ouichi teaches a similar reference device **(5) in Col. 9 Lines 33-37** that is foldable (**Col. 9 Lines 56-59**) and comprises a screen. In view of the teachings of Doi and Ouichi, as a whole, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the reference device of Doi with the reference device of Ouichi as an alternative implementation of analogous structures for the same purpose of measuring size.

32. Doi also discloses that said surgical instrument comprises a guide barrel **(shaded barrel in Fig. 2 and Col. 2 Lines 18-20)** and a shank **(1, 1', 2)** sliding inside said guide barrel, the barrel being able to be inserted inside the body and having a proximal end in the vicinity of the handle and an opposite distal end which is open, wherein the shank has a head-piece **(10, 12, 12a) of Fig.1 and Col. 2 Lines 62-27** with support arms **(4)**. Additionally, Ouichi discloses that said screen is capable of being supported with support arms **(1, 2) in Fig. 2**. In view of the teachings of Doi and Ouichi, as a whole, it would have been obvious to one of ordinary skill in the art at the time of

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invention was made to not only modify the reference device of Doi with the screen of Ouichi as an alternative implementation of analogous structures for the same purpose, but also in such a way that the deformable screen is supported with the support arms of Doi as evidenced by Tovey.

33. Tovey is applied as a secondary teaching to evidence the level of skill in the art. In particular, Tovey teaches a similar surgical instrument, wherein said screen is connected to said support arms at distal sections **as shown in Figs. 1-4**. In view of the teachings of Doi, Ouichi and Tovey, as a whole, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the reference device size of Doi and Ouichi to be connected at distal sections as taught by Tovey, as an exemplary implementation of analogous supporting arms and screen for deployment at the distal end being able to be retracted and deployed.

34. Ouichi discloses that multiple screen sizes can be used **in Col. 10 Lines 13-15**. However, Doi remains silent as to the reference device being larger than a diameter of said guide barrel. Abe is applied as a secondary teaching to evidence the level of skill in the art. In particular, Abe teaches a similar reference device to Doi, wherein the reference device, when in said unfolded state, is larger than a diameter of said guide barrel **as shown in Fig. 4**. In view of the teachings of Doi, Ouichi, Tovey and Abe, as a whole, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the reference device size of Doi and Ouichi with the reference device size of Abe as an alternative implementation of analogous structures for the same purpose of measuring size in order to measure larger lesions.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. **See the enclosed 892 form. 2002/0026093 and 6,459,481 are cited to show similar screens.** The prior art should be considered to define the claims over the art of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM CHOU whose telephone number is (571)270-3367. The examiner can normally be reached on 8:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/WILLIAM CHOU/
Examiner, Art Unit 3779

/Philip R Smith/
Primary Examiner, Art Unit 3779